

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOHN DOE,

Plaintiff,

-against-

NEW YORK STATE DEPARTMENT OF HEALTH
and HOWARD A. ZUCKER in his official capacity as
Commissioner of the New York State Department of Health,

Defendants.

COMPLAINT

JURISDICTION AND VENUE

1. This Court has jurisdiction under 28 U.S.C. Section 1331.
2. Venue is proper in this District pursuant to 28 U.S.C. Section 1391(b)(1).

PARTIES

3. Plaintiff, John Doe (“Doe”), is a pseudonymous natural person who resides in the State of New York.

4. Defendant New York State Department of Health (“DOH”) is an executive agency of the State of New York, and maintains an office at 90 Church Street, New York, New York 10007.

5. Defendant Howard A. Zucker is the Commissioner of the DOH.

ALLEGATIONS

6. Numerous clinical-laboratory tests reveal evidence of disease or of other medical conditions (“Lab Tests”).

7. Many businesses sell Lab Tests to consumers and provide the results of such tests directly and solely to such consumers.

8. Many of the Lab Tests described in the preceding paragraph are sold without any involvement by a physician, a physician’s agent, or other persons authorized by law to employ the

results of Lab Tests in the conduct of their practice or in the fulfillment of their official duties (“Medical Providers”).

9. Doe wishes to purchase, and receive at his residence, Lab Tests as described in the preceding paragraph (“Direct-to-Consumer Lab Tests”).

10. The United States Food and Drug Administration (“FDA”) has the authority to approve the sale of Direct-to-Consumer Lab Tests. *See* 21 U.S.C. §§ 321(h)(2), 393(b)(1).

11. The FDA has approved the sale of the Direct-to-Consumer Lab Tests that Doe wishes to purchase and thereupon receive at his residence.

12. New York State prohibits non-Medical Providers of Lab Tests from reporting the results of such tests directly and solely to the purchasers of the tests. *See* 10 N.Y.C.R.R. § 58-1.8 (the “New York State Prohibition”).

13. As a result of the New York State Prohibition, non-Medical Providers of Direct-to-Consumer Lab Tests do not ship such tests to New York State.

LEGAL ASSERTIONS

14. The New York State Prohibition is un-Constitutional because it violates the Supremacy Clause of the United States Constitution, which provides that Constitutionally valid federal law “shall be the supreme Law of the Land[,] . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const., Art. VI, cl. 2.

CLAIMS FOR RELIEF

Plaintiff is entitled to the following relief:

(a) a judgment declaring, pursuant to 28 U.S.C. Section 2201(a), that the New York State Prohibition is un-Constitutional; and

(b) a writ of mandamus, pursuant to 28 U.S.C. Section 1361, directing Defendants not to enforce the New York State Prohibition.

Dated: June 23, 2020

Respectfully submitted,

s/ **Todd C. Bank**

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